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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

In re ARDELYX, INC.	Case No. 4:21-cv-05868-HSG CLASS ACTION **AMENDED CLASS ACTION COMPLAINT** DEMAND FOR JURY TRIAL

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Lead Plaintiff Jatin Malhotra ("Plaintiff") makes the following allegations, individually and on behalf of all others similarly situated, by and through Plaintiff's counsel, upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, *inter alia*, counsel's investigation, which included, among other things, review and analysis of: (i) regulatory filings made by Ardelyx Inc. ("Ardelyx" or "Company") with the U.S. Securities and Exchange Commission ("SEC"); (ii) press releases and media reports issued and disseminated by the Company; and (iii) analyst reports, media reports, and other publicly disclosed reports and information about the Company. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein, after a reasonable opportunity for discovery.

SUMMARY OF THE ACTION

1. Plaintiff brings this federal securities action under §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5) on behalf of a class consisting of all persons and entities, other than Defendants and their affiliates, who purchased or otherwise acquired Ardelyx securities between August 6, 2020 and July 19, 2021, inclusive ("Class Period"), and who were damaged as a result of Defendants' violations of the Exchange Act ("Class").

2. Ardelyx is a publicly traded biopharmaceutical company. During the relevant period, the focus of its business was developing and commercializing a drug called tenapanor to treat elevated serum phosphorus – a condition called hyperphosphatemia – in adult patients with chronic kidney disease ("CKD") on dialysis.

3. If approved for that indication, tenapanor would represent a first-in-class treatment for the control of serum phosphorus in adult patients with CKD on dialysis because of its novel mechanism of action. While existing drugs on the market for the treatment of hyperphosphatemia in adult CKD patients on dialysis act through the mechanism of binding to phosphates, tenapanor purportedly acts through the mechanism of inhibiting the cellular uptake of phosphates.

4. On or about June 30, 2020, Ardelyx submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") to obtain approval to sell and market tenapanor for the treatment of hyperphosphatemia in adult CKD patients on dialysis. Defendants told the public about that submission on August 6, 2020, when the Class Period commences. The FDA accepted, or agreed to review, Ardelyx's NDA on or about September 15, 2020, and set a Prescription Drug User Fee Act ("PDUFA") date of April 29, 2021. A PDUFA date is the date by which the FDA must respond to an NDA.

5. Because Defendants considered tenapanor their leading product candidate during the relevant period, the fate of Ardelyx's tenapanor NDA – *i.e.*, whether the FDA would approve or reject it – was integral to the valuation and future success of Ardelyx securities. To that end, in connection with the FDA agreeing to review its tenapanor NDA, Defendants repeatedly emphasized to investors the commercial promise of the drug, which they attributed in large measure to the purportedly resounding successes of the Phase 3 clinical trials the Company used in support of the NDA.

6. Indeed, at every turn during the Class Period, Defendants trumpeted the successes of the relevant Phase 3 clinical trials, painting for investors a false picture in which FDA approval of the tenapanor NDA was shored up by the purportedly successful nature of the trials, from design to results. Defendants repeatedly brandished the FDA's acceptance and review of the NDA, supported by so-called "successful" Phase 3 studies, in subsequently filed quarterly reports, the Company's 2020 Annual Report, relevant press releases, and investor calls.

7. Even when the FDA asked Ardelyx to provide additional information related to its clinical data – which reportedly occurred on or about April 29, 2021, after the FDA and Company had begun labeling talks, and which delayed the PDUFA date by three months – Defendants continued to hype the "positive" clinical trial results underlying the tenapanor NDA. According to Defendants, despite the uncharacteristic timing of the FDA's request for clarifying information, the trials still unequivocally demonstrated tenapanor's "clinical safety and efficacy." At no point did Defendants state or suggest that serious deficiencies in Ardelyx's clinical trial data likely

doomed the tenapanor NDA. Rather, Defendants claimed that the FDA's request was merely because the agency needed help to "better understand the clinical data in light of tenapanor's novel mechanism of action as compared to approved therapies," and tacked on citation to the generalized "impact that the COVID-19 pandemic has had on the operations of the agency."

8. Unfortunately for investors, the reality-check that would bring Defendants' unduly rosy narrative back to Earth – and cause the price of Ardelyx shares to plummet – came to a head on July 19, 2021. That day, Ardelyx announced in a press release that it had received a letter from the FDA dated July 13, 2021, in which the agency stated it had found deficiencies in the tenapanor NDA that precluded discussion of the would-be labeling and post-marketing requirements for the drug. Critically, the FDA said it detected "deficiencies" in the clinical data Ardelyx had provided with respect to both "***the size of the treatment effect and its clinical relevance***," at minimum. [Emphasis added.]

9. The Phase 3 trials offered in support of the tenapanor NDA ("Phase 3 Trials") all used surrogate endpoints to predict clinical outcomes instead of measuring the clinical outcomes themselves. With respect to clinical trial endpoints, a clinical outcome directly measures the proposed benefit of a therapy (*e.g.*, reduced morbidity or mortality), while a surrogate endpoint uses another marker (*e.g.*, levels of serum phosphate) to predict the expected clinical benefit. As a general matter, clinical outcomes are the preferred measure of the clinical effect of a therapy, and surrogate endpoints are an alternative available in certain circumstances.

10. In many instances, the difference between those two types of clinical endpoints materially informs the strength and meaningfulness of the hypotheses that clinical trials set out to support. That is precisely what happened with the tenapanor NDA, at least according to Defendant Raab, who stated months later at a conference with investors, "but for the fact that ***this division*** [of the FDA] ***is not keen on surrogate endpoints***," the NDA would have been approved. [Emphasis added.]

11. But rather than acknowledge responsibility for dropping the ball on the clinical trials supporting the tenapanor NDA, or for misleading investors as a result, Defendants have

attempted to blame the FDA for the problems they caused. Defendants have accused the FDA of performing a complete 180 with respect to the clinical trial data, alleging the FDA "***moved the*** . . . ***goalposts*** on" them during the pendency of the NDA – that is, even though the FDA purportedly ***collaborated and agreed*** with the Company on the designs of the trials at issue. [Emphasis added.]

12. Immediately following the Company's July 19, 2021 disclosure regarding the deficiencies of the clinical trial data offered to support the tenapanor NDA, market analysts cut their price targets and downgraded the Company's rating. Piper Sandler, for example, rated Ardelyx neutral (down from a buy-equivalent rating) and wrote, "we struggle to see a path forward for Tenapanor." Raymond James, another analyst, reset the Company's price target to $4 from $14 per share.

13. The Company's share price likewise plunged, falling $5.69 per share – or nearly 74% – in a single day, to close at $2.01 per share on July 20, 2021, before falling another 4.5% by market close on July 21, 2021.

14. Throughout the Class Period, Defendants painted an unduly rosy picture of the data from the Phase 3 Trials that Ardelyx submitted in support of its tenapanor NDA despite knowing that the data's reliance on the surrogate endpoint of serum phosphates – which had never been used in support of a successful drug application for the indication of hyperphosphatemia where, as here, the drug's mechanism of action was inhibiting phosphate uptake – substantially undermined the data's ability to show a clinically relevant or efficacious treatment effect that would deliver, or be likely to deliver, FDA approval of a first-in-class medicine. Defendants possessed, were in control over, and, as a result, knew (or had reason to know) that the data from the Phase 3 Trials submitted to support the tenapanor NDA was not nearly as strong as they serially represented to investors.

15. This lawsuit seeks to recover damages sustained as a result of Defendants' wrongdoing.

JURISDICTION AND VENUE

16. The claims asserted herein arise under §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)), and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the Exchange Act (15 U.S.C. §78aa).

18. This Court has jurisdiction over each of the Defendants named herein because each is an individual or a corporation who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

19. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b). During the relevant period, Defendants conducted business in this District, and a substantial part of the events or omissions giving rise to the claims in this action – including Defendants' preparation and dissemination of materially false and misleading information as alleged herein – occurred in this District.

20. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the U.S. mail, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

A. Plaintiff

21. Lead Plaintiff Jatin Malhotra, as set forth in his previously filed certification, acquired and held shares of Ardelyx common stock at artificially inflated prices during the Class Period, and has been damaged as a result of the violations of the federal securities law alleged herein. (*See* Dkt. No. 45-2.)

B. Defendants

22. Defendant Ardelyx is a specialized biopharmaceutical company incorporated under the laws of the state of Delaware. At all relevant times prior to October 2021, Ardelyx was co-headquartered in Fremont, California (at 34175 Ardenwood Boulevard, Fremont, California 94555) and Waltham, Massachusetts (at 400 Fifth Avenue, Suite 210, Waltham, Massachusetts 02451). As of October 2021, and currently, the Company maintains its headquarters in Waltham, Massachusetts. Ardelyx's common stock is listed on the NASDAQ under the ticker symbol "ARDX."

23. Defendant Mike Raab was, throughout the Class Period and at all relevant times, President and Chief Executive Officer of the Company, positions he held since March 2009. Defendant Raab also serves as a director on Ardelyx's Board of Directors.

24. Defendant Justin Renz was, throughout the Class Period and at all relevant times, Chief Financial Officer of the Company, a position he held since June 2020. Together, Defendants Raab and Renz are referred to herein as the "Individual Defendants."

25. The Individual Defendants, because of their positions at the Company, possessed the power and authority to control the content and form of the Company's annual reports, quarterly reports, press releases, investor presentations, and other materials provided to the SEC, securities analysts, money and portfolio managers and investors, *i.e.*, the market. The Individual Defendants authorized the publication of the documents, presentations, and materials alleged herein to be misleading prior to its issuance and had the ability and opportunity to prevent the issuance of these false statements or to cause them to be corrected. Because of their position with the Company and access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public and that the positive representations being made were false and misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

I. ARDELYX AND TENAPANOR

26. Founded in 2007, Ardelyx is a biotechnology company focused on developing and commercializing therapies for persons with kidney and cardiorenal disease. Ardelyx has been publicly traded since June 2014 and has not earned a profit in any fiscal year. Accordingly, at all relevant times, Ardelyx's financial well-being heavily depended on the commercial success of tenapanor for the treatment of hyperphosphatemia in adults with CKD on dialysis.

27. Ardelyx considers tenapanor its "lead product candidate." Ardelyx initially began developing tenapanor in or about 2009 to treat irritable bowel syndrome associated with constipation. For that indication only, Ardelyx obtained FDA approval in or about September 2019 to market and sell tenapanor in the United States, but the Company has neither commercialized nor generated any revenue from its sale for that indication yet.

28. As relevant here, Ardelyx has advanced another indication for tenapanor, namely, for the treatment of hyperphosphatemia in adult CKD patients on dialysis.

29. In the context of that indication, tenapanor represents a first-in-class therapy because of its novel mechanism of action. Extant medicines that treat hyperphosphatemia in adult CKD patients on dialysis act through the mechanism of binding to phosphates that enter the body. Tenapanor, by contrast, acts through the mechanism of inhibiting the paracellular uptake of phosphates. According to Ardelyx, tenapanor has "a unique mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3, or NHE3," resulting in the "tightening of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption."

30. If approved, according to Ardelyx, tenapanor "would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake," and "could greatly improve patient adherence and compliance with one single pill dosed twice daily in contrast to current therapies where typically multiple pills are taken before every meal."

31. Thus, as presented by Defendants, obtaining FDA approval for tenapanor for treating hyperphosphatemia represented, and continues to represent, a lucrative commercial opportunity. The importance of that opportunity for Ardelyx was compounded by the Company's historical inability to report a profitable quarter as a publicly traded company.

II. ARDELYX'S NDA FOR TENAPANOR FOR HYPERPHOSPHATEMIA

32. On August 6, 2020 – the date on which the Class Period begins – in a press release titled "Ardelyx Reports Second Quarter 2020 Financial Results and Recent Business Highlights," Ardelyx announced that on June 30, 2020, it submitted an NDA to the FDA for tenapanor for the treatment of hyperphosphatemia in adult CKD patients on dialysis. An NDA is the means by which a drug sponsor formally asks the FDA to approve a new drug for marketing and sale in the United States with respect to a given indication. The Company reported substantially the same news in its quarterly report on Form 10-Q for the period ending June 30, 2020, which it filed with the SEC the same day.

33. On September 15, 2020, Ardelyx announced that the FDA had accepted, or agreed to review, its NDA for tenapanor for the treatment of hyperphosphatemia in adult CKD patients on dialysis. The Company did so in a press release titled "Ardelyx Announces FDA Acceptance for Filing of Its New Drug Application of Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis." Also in that press release, Ardelyx relayed that the FDA had set a PDUFA date – *i.e.*, the date by which the FDA would respond to the NDA – of April 29, 2021.

34. Ardelyx presented tenapanor to the FDA based on a Phase 3 clinical trial program consisting of what it described as "three successful Phase 3 trials involving over 1,000 patients that evaluated the use of tenapanor." Phase 3 clinical studies also are known as "pivotal" studies because they generally contain the data that the FDA will use to determine whether to approve a proffered therapy for a given indication.

35. In general, a Phase 3 clinical trial uses a particular clinical trial endpoint to measure the results of the trial. An endpoint that directly measures the proposed clinical benefit of a therapy, such as reduced morbidity or mortality, is called a clinical outcome endpoint. An endpoint

that measures another metric, such as levels of serum phosphorus, is called a surrogate endpoint. A surrogate endpoint, in turn, must be shown to reliably predict the clinical benefit of a proposed therapy by virtue of the measured changes in the surrogate endpoint because, by design, a surrogate endpoint does not directly measure the clinical benefit.

36. Certain surrogate endpoints belong to the subclass called biomarkers. In general, a biomarker is a defined characteristic that is measured objectively as an indicator of the body's response to an exposure or intervention, including a therapeutic intervention.

37. Given the inherent limitations on the utility of surrogate endpoints (and the clinical trial data that relies on them), the FDA publishes and maintains a table of surrogate endpoints "that have either been already used in development programs for drugs that have been approved, or surrogate endpoints that [the] FDA has indicated acceptance of in guidance[] or other documents."[1] The purpose of that table is to "provide[] valuable information for drug developers on endpoints that may be considered and discussed with [the] FDA for individual development programs," and to "facilitate consideration of potential surrogate endpoints when developers are designing their drug development programs." The FDA also is required by statute to publish that information.

38. The FDA instructs that the acceptability of using even those surrogate endpoints included on its table depends "in part on the disease, studied patient population, ***therapeutic mechanism of action***, and availability of current treatments." As the FDA instructs further: "A particular surrogate endpoint that may be appropriate for use in a particular drug or biologic clinical development program, ***should not be assumed to be appropriate for use in a different program that is in a different clinical setting***." [Emphasis added.].

39. Each of the three Phase 3 trials that Ardelyx used to support the tenapanor NDA – collectively referred to herein as the Phase 3 Trials – used a surrogate endpoint instead of a clinical outcome endpoint. The relevant surrogate endpoints all related to levels of serum phosphates measured in trial participants (which may be further characterized as a biomarker). That means

[1] *Table of Surrogate Endpoints That Were the Basis of Drug Approval or Licensure*, Food & Drug Admin. (Feb. 28, 2022), https://www.fda.gov/drugs/development-resources/table-surrogate-endpoints-were-basis-drug-approval-or-licensure.

the Phase 3 Trials measured the changes in serum phosphorus among participants that could be attributed to the use of tenapanor. The Phase 3 Trials did not measure whether or to what extent any clinical benefits flowed from those changes in serum phosphorus, such as reduced morbidity or mortality.

40. As relevant here, however, "serum phosphates" appears on the FDA's table of surrogate endpoints for the indication of hyperphosphatemia only where the "[d]rug mechanism of action" is phosphate binding. Put differently, there is no precedent for the successful use of serum phosphates as a clinical endpoint where, as here, the drug's mechanism of action is inhibiting phosphate uptake – rather than binding to phosphates – to treat hyperphosphatemia.

41. On April 29, 2021, roughly ten months after Ardelyx submitted the tenapanor NDA, the Company announced that the FDA pushed back the PDUFA date it initially had set by three months. In the relevant press release the Company issued, titled "Ardelyx Announces Extension of the PDUFA Review Period for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis," Ardelyx stated that the FDA had "made a recent information request that required the company to submit additional analyses to help the agency better understand the clinical data in light of tenapanor's novel mechanism of action as compared to approved therapies." According to Ardelyx, that information request came after the parties already had begun "constructive labeling discussions" regarding tenapanor.

42. The next key update Ardelyx provided on the tenapanor NDA occurred several months later, on July 19, 2021, when the Company announced that the FDA had sent it a letter six days earlier (on July 13, 2021) in which the agency "identified deficiencies that preclude[d] discussion of labeling and post-marketing requirements" for tenapanor. The "deficiencies" the FDA identified included, according to Ardelyx, "the size of the treatment effect and its clinical relevance" pursuant to the Phase 3 Trials. The Company made that update in a press release titled "Ardelyx Provides Regulatory Update on New Drug Application for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis."

43. As detailed herein, at all relevant times, Defendants knew (or recklessly disregarded) that the Phase 3 Trials' use of serum phosphates as surrogate endpoints – which never had been "the basis of approval or licensure (as applicable) of a drug" advanced to treat hyperphosphatemia through the mechanism of action that tenapanor used, and which the FDA had not "indicated acceptance of in guidance[] or other documents" as a validated endpoint in that context – materially weakened the ability of the clinical data in the tenapanor NDA to demonstrate a clinically relevant treatment effect of the drug that would deliver, or be likely to deliver, FDA approval of a first-in-class medicine. Because demonstrating such clinical relevance was integral to the tenapanor NDA, in turn, Defendants misled investors about the likelihood that the FDA would approve the NDA.

III. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS

44. Throughout the Class Period, Defendants painted an unduly rosy picture of the data from the Phase 3 Trials that Ardelyx submitted in support of its tenapanor NDA despite knowing that the data's reliance on surrogate endpoints substantially undermined its ability to show a clinically relevant treatment effect that would deliver, or be likely to deliver, FDA approval of a first-in-class medicine.

A. August 6, 2020 Quarterly Report

45. On August 6, 2020, when the Class Period begins, Ardelyx filed with the SEC its quarterly report on Form 10-Q for the period ending June 30, 2020 ("2Q20 10-Q"). In relevant part, with respect to the tenapanor NDA and underlying Phase 3 Trials, the 2Q20 10-Q stated:

> Our portfolio is led by the development of tenapanor, a first-in-class medicine for the control of serum phosphorus in adult patients with CKD on dialysis, for which we completed the Phase 3 clinical program and have submitted a New Drug Application ("NDA") to the United States Food and Drug Administration ("FDA") on June 30, 2020. Based on standard FDA review timelines, we expect to receive notification from the FDA on the acceptance of the filing for substantive review by early September 2020. Tenapanor for the control of serum phosphorus has a unique mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3 ("NHE3"). This results in the tightening of the epithelial cell junctions, thereby significantly reducing paracellular uptake of phosphate, the primary pathway of phosphate absorption. ***Three successful Phase 3 studies demonstrating tenapanor's ability to reduce phosphate levels, as either***

> ***monotherapy or as part of a dual mechanism approach with phosphate binders, have been reported***.
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> We have evaluated tenapanor in a Phase 3 program for the control of serum phosphorus in CKD patients on dialysis. In December 2019, ***we reported statistically significant topline efficacy results from our second monotherapy Phase 3 clinical trial***, the PHREEDOM trial. The PHREEDOM trial followed ***a successful monotherapy Phase 3 clinical trial completed in 2017, which achieved statistical significance for the primary endpoint***. PHREEDOM is a one-year study with a 26-week open-label treatment period and a 12-week double-blind, placebo-controlled randomized withdrawal period followed by a 14-week open-label safety extension period. An active safety control group, for safety analysis only, received sevelamer, open-label, for the entire 52-week study period. Patients completing the PHREEDOM trial from both the tenapanor arm and the sevelamer active safety control arm had the option to participate in NORMALIZE, an ongoing open-label 18-month extension study.
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> In June 2020, we announced positive results from a planned interim data analysis from our ongoing NORMALIZE Phase 4 study evaluating tenapanor, as monotherapy or in combination with sevelamer, to achieve serum phosphorus levels in the normal range (2.5 – 4.5 mg/dL) in patients with CKD on dialysis. The NORMALIZE extension study allowed patients from our PHREEDOM study to continue therapy with tenapanor and enabled those patients in the PHREEDOM safety control arm receiving sevelamer carbonate to transition to tenapanor. ***The data from the planned interim analysis demonstrated that the foundational use of tenapanor as monotherapy or in combination with sevelamer carbonate produces a significant phosphorus-lowering effect*** with a mean serum phosphorous reduction of 2.33 mg/dL, from a mean baseline phosphorus of 7.27 mg/dL at the beginning of the PHREEDOM trial to a mean of 4.94 mg/dL at the time of this analysis. . . .
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> . . . .
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> Tenapanor, if approved, would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake. It is not a phosphate binder. Tenapanor is a novel, potent, small molecule, that ***has been shown in the phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach***. Additionally, as such we believe tenapanor could greatly improve patient adherence and compliance with one single pill dosed twice daily in contrast to current therapies where typically multiple pills are taken before every meal.

[Emphasis added.]

46. The statements set out in ¶45 were materially false, misleading, incomplete, and inaccurate – both individually and in combination – because they conveyed that (i) in support of

the tenapanor NDA, Ardelyx had provided data from "[t]hree successful Phase 3 studies demonstrating tenapanor's ability to reduce phosphate levels, as either monotherapy or as part of a dual mechanism approach with phosphate binders"; (ii) one such Phase 3 Trial, PHREEDOM, generated "statistically significant topline efficacy results"; (iii) another such Phase 3 Trial, described as a "successful monotherapy Phase 3 clinical trial," "achieved statistical significance for the primary endpoint"; (iv) Ardelyx had "demonstrated that the foundational use of tenapanor as monotherapy or in combination with sevelamer carbonate produces a significant phosphorus-lowering effect"; and (v) tenapanor "has been shown in the phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach." In reality, as Defendants knew or recklessly disregarded, the Phase 3 Trials did not demonstrate that tenapanor produced a clinically relevant or efficacious treatment effect in adult CKD patients on dialysis suffering from hyperphosphatemia, whether under a monotherapy or dual-mechanism approach. In fact, as Defendants knew and failed to disclose in connection with those representations, the Phase 3 Trials measured only the surrogate endpoint of serum phosphates, which (i) never had been "the basis of approval or licensure (as applicable) of a drug" advanced to treat hyperphosphatemia through the mechanism of action that tenapanor used; (ii) the FDA had not "indicated acceptance of in guidance[] or other documents" as a validated endpoint in that context; and (iii) greatly increased the risk that the FDA would reject the tenapanor NDA (which it did). Defendants had a duty to disclose that key distinction to make their statements about the relevant clinical data not misleading, and because they chose to speak about the purported findings of the relevant clinical data and thus had to speak the complete truth on that topic.

B. August 6, 2020 Press Release

47. The same day, in the Company's press release accompanying its 2Q20 10-Q, Ardelyx announced that it had submitted the tenapanor NDA to the FDA "for the review of tenapanor as a first-in-class therapy to control serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis." Quoting Defendant Raab, the press release stated:

> "Over the last quarter, we continued to make critical progress towards our goal of providing our first-in-class therapy tenapanor to adult CKD patients on dialysis

> with elevated serum phosphorus, a condition, despite traditional therapies, that has been associated with poor survival outcomes," said Mike Raab, president and chief executive officer of Ardelyx. "This past June, we submitted a New Drug Application to the FDA for this indication, and we expect to receive notification of its acceptance for substantive review and our PDUFA date by early September. ***As part of our filing, we included additional, robust data reconfirming tenapanor's ability to lower and control serum phosphorous levels at a rate better than those reported with phosphate binders alone***. In addition, during the quarter, we augmented our senior leadership team with the hiring of an experienced chief commercial officer and chief financial officer as we prepare for launch and evolving into a revenue-generating company."

[Emphasis added.]

48. Under the heading "Recent Business and Pipeline Updates," the August 6, 2020 press release also stated that the NDA "filing is supported by ***three successful Phase 3 studies*** demonstrating tenapanor's ability to reduce phosphate levels, with two trials evaluating tenapanor as a monotherapy and the third evaluating tenapanor as part of a dual mechanism approach with phosphate binders." The press release also reported "additional positive data from the ongoing NORMALIZE Phase 4 study," which was an extension of one of the three Phase 3 Trials that remained ongoing. [Emphasis added.]

49. The statements set out in ¶¶47–48 were materially false, misleading, incomplete, and inaccurate – both individually and in combination – because they conveyed that in support of the tenapanor NDA Ardelyx provided (i) "robust data reconfirming tenapanor's ability to lower and control serum phosphorus levels at a rate better than those reported with phosphate binders alone"; and (ii) data from "three successful Phase 3 studies demonstrating tenapanor's ability to reduce phosphate levels." In reality, as Defendants knew or recklessly disregarded, the Phase 3 Trials did not demonstrate that tenapanor produced a clinically relevant treatment effect in adult CKD patients on dialysis suffering from hyperphosphatemia, whether under a monotherapy or dual-mechanism approach. In fact, as Defendants knew and failed to disclose in connection with those representations, the Phase 3 Trials measured only the surrogate endpoint of serum phosphates, which (i) never had been "the basis of approval or licensure (as applicable) of a drug" advanced to treat hyperphosphatemia through the mechanism of action that tenapanor used; (ii) the

FDA had not "indicated acceptance of in guidance[] or other documents" as a validated endpoint in that context; and (iii) greatly increased the risk that the FDA would reject the tenapanor NDA (which it did). Defendants had a duty to disclose that key distinction to make their statements about the relevant clinical data not misleading, and because they chose to speak about the purported findings of the relevant clinical data and thus had to speak the complete truth on that topic.

C. September 15, 2020 Press Release

50. On September 15, 2020, Ardelyx announced in a press release that the FDA had accepted, or agreed to review, its NDA for tenapanor for the treatment of hyperphosphatemia in adult CKD patients on dialysis. In so doing, the Company repeated the following misleading representation it had made little more than one month earlier:

> ***The NDA is supported by three successful Phase 3 trials*** involving over 1,000 patients that evaluated the use of tenapanor, which included: two monotherapy trials, including a long-term study, to control serum phosphorus in patients with CKD on dialysis, and one trial using a dual-mechanism approach in dialysis patients who had difficult-to-control hyperphosphatemia (≥5.5 mg/dL) despite phosphate binder therapy.

[Emphasis added.]

51. The statements set out in ¶50 were materially false, misleading, incomplete, and inaccurate – both individually and in combination – because they conveyed that in support of the tenapanor NDA Ardelyx provided data from "three successful Phase 3 trials." In reality, as Defendants knew or recklessly disregarded, the Phase 3 Trials did not demonstrate that tenapanor produced a clinically relevant treatment effect in adult CKD patients on dialysis suffering from hyperphosphatemia, whether under a monotherapy or dual-mechanism approach. In fact, as Defendants knew and failed to disclose in connection with those representations, the Phase 3 Trials measured only the surrogate endpoint of serum phosphates, which (i) never had been "the basis of approval or licensure (as applicable) of a drug" advanced to treat hyperphosphatemia through the mechanism of action that tenapanor used; (ii) the FDA had not "indicated acceptance of in guidance[] or other documents" as a validated endpoint in that context; and (iii) greatly increased the risk that the FDA would reject the tenapanor NDA (which it did). Defendants had a duty to

disclose that key distinction to make their statements about the relevant clinical data not misleading, and because they chose to speak about the purported findings of the relevant clinical data and thus had to speak the complete truth on that topic.

D. November 5, 2020 Quarterly Report

52. On November 5, 2020, Ardelyx filed with the SEC on Form 10-Q its third quarter 2020 financial results ("3Q20 10-Q"), repeating substantially the same claims made in the Company's 2Q20 10-Q with respect to the tenapanor NDA and underlying Phase 3 Trials. In relevant part, the 3Q20 10-Q stated:

> ***The NDA is supported by three successful Phase 3 trials*** involving over 1,000 patients that evaluated the use of tenapanor for the control of serum phosphorus in CKD patients on dialysis, with two trials evaluating tenapanor as monotherapy and one trial evaluating tenapanor as part of a dual mechanism approach with binders.
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> In December 2019, ***we reported statistically significant topline efficacy results from our second monotherapy Phase 3 clinical trial***, the PHREEDOM trial, which evaluated tenapanor for the control of serum phosphorus in CKD patients on dialysis. The PHREEDOM trial followed ***a successful monotherapy Phase 3 clinical trial completed in 2017, which achieved statistical significance for the primary endpoint***. PHREEDOM is a one-year study with a 26-week open-label treatment period and a 12-week double-blind, placebo-controlled randomized withdrawal period followed by a 14-week open-label safety extension period. An active safety control group, for safety analysis only, received sevelamer, open-label, for the entire 52-week study period. Patients completing the PHREEDOM trial from both the tenapanor arm and the sevelamer active safety control arm had the option to participate in NORMALIZE, an ongoing open-label 18-month extension study.
>
> In June 2020, we announced positive results from a planned interim data analysis from our ongoing NORMALIZE extension study evaluating tenapanor, as monotherapy or in combination with sevelamer, to achieve serum phosphorus levels in the normal range (2.5 – 4.5 mg/dL) in patients with CKD on dialysis. The NORMALIZE extension study allowed patients from our PHREEDOM study to continue therapy with tenapanor and enabled those patients in the PHREEDOM safety control arm receiving sevelamer carbonate to transition to tenapanor. ***The data from the planned interim analysis demonstrated that the foundational use of tenapanor as monotherapy or in combination with sevelamer carbonate produces a significant phosphorus-lowering effect*** with a mean serum phosphorous reduction of 2.33 mg/dL, from a mean baseline phosphorus of 7.27 mg/dL at the beginning of the PHREEDOM trial to a mean of 4.94 mg/dL at the time of this analysis. . . .

. . . .

> Tenapanor, if approved, would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake. It is not a phosphate binder. Tenapanor is a novel, potent, small molecule, that ***has been shown in the phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach***. Additionally, we believe tenapanor could greatly improve patient adherence and compliance with one single pill dosed twice daily in contrast to current therapies where typically multiple pills are taken before every meal.

[Emphasis added.]

53. The statements set out in ¶52 were materially false, misleading, incomplete, and inaccurate – both individually and in combination – because they conveyed that (i) the tenapanor "NDA is supported by three successful Phase 3 trials"; (ii) one such Phase 3 Trial, PHREEDOM, generated "statistically significant topline efficacy results"; (iii) another such Phase 3 Trial, described as a "successful monotherapy Phase 3 clinical trial," "achieved statistical significance for the primary endpoint"; (iv) Ardelyx "demonstrated that the foundational use of tenapanor as monotherapy or in combination with sevelamer carbonate produces a significant phosphorus-lowering effect"; and (v) tenapanor "has been shown in the phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach." In reality, as Defendants knew or recklessly disregarded, the Phase 3 Trials did not demonstrate that tenapanor produced a clinically relevant or efficacious treatment effect in adult CKD patients on dialysis suffering from hyperphosphatemia, whether under a monotherapy or dual-mechanism approach. In fact, as Defendants knew and failed to disclose in connection with those representations, the Phase 3 Trials measured only the surrogate endpoint of serum phosphates, which (i) never had been "the basis of approval or licensure (as applicable) of a drug" advanced to treat hyperphosphatemia through the mechanism of action that tenapanor used; (ii) the FDA had not "indicated acceptance of in guidance[] or other documents" as a validated endpoint in that context; and (iii) greatly increased the risk that the FDA would reject the tenapanor NDA (which it did). Defendants had a duty to disclose that key distinction to make their statements about the relevant clinical data not

misleading, and because they chose to speak about the purported findings of the relevant clinical data and thus had to speak the complete truth on that topic.

E. November 5, 2020 Press Release

54. In the November 5, 2020 press release accompanying the 3Q20 10-Q – titled "Ardelyx Reports Third Quarter 2020 Financial Results and Business Highlights" – Ardelyx again used the relevant clinical trial data as a centerpiece. Quoting Defendant Raab, the press release stated:

> "The FDA's acceptance of our New Drug Application for tenapanor is a major milestone that continues our progress toward the potential launch of this novel therapeutic for the many dialysis patients who struggle with controlling hyperphosphatemia," said Mike Raab, president and chief executive officer of Ardelyx. "Our commitment to this field was further highlighted in ***clinical data presented at ASN Kidney Week 2020 generated by Ardelyx and our Japanese partner KKC, supporting the clinical safety and efficacy of tenapanor and reinforcing its potential to transform the treatment landscape for patients***."

[Emphasis added.]

55. Under the heading "Recent Business and Pipeline Updates," the November 5, 2020 press release also stated:

> The United States Food and Drug Administration (FDA) accepted the New Drug Application (NDA) for tenapanor to control serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis with a Prescription Drug User Fee Act ("PDUFA") goal date of April 29, 2021. ***The filing was supported by three successful Phase 3 studies demonstrating tenapanor's ability to reduce phosphate levels***, with two trials evaluating tenapanor as a monotherapy and the third evaluating tenapanor as part of a dual mechanism approach with phosphate binders.
>
> ***Presented new clinical data supporting the clinical safety and efficacy of tenapanor*** at ASN Kidney Week 2020. Three poster presentations highlighted data from Phase 3 trials conducted by Ardelyx, including the BLOCK, AMPLIFY and PHREEDOM studies. Additionally, the company's partner for tenapanor in Japan, Kyowa Kirin Co., Ltd., presented the results from two Phase 2 studies evaluating the efficacy and safety of tenapanor in Japanese patients on hemodialysis

[Emphasis added.]

56. The statements set out in ¶¶54–55 were materially false, misleading, incomplete, and inaccurate – both individually and in combination – because they conveyed that (i) Ardelyx

had generated "new clinical data supporting the clinical safety and efficacy of tenapanor" and further "reinforcing its potential to transform the treatment landscape for patients"; and (ii) in support of the tenapanor NDA Ardelyx provided data from "three successful Phase 3 studies." In reality, as Defendants knew or recklessly disregarded, the Phase 3 Trials did not demonstrate that tenapanor produced a clinically relevant or efficacious treatment effect in adult CKD patients on dialysis suffering from hyperphosphatemia, whether under a monotherapy or dual-mechanism approach. In fact, as Defendants knew and failed to disclose in connection with those representations, the Phase 3 Trials measured only the surrogate endpoint of serum phosphates, which (i) never had been "the basis of approval or licensure (as applicable) of a drug" advanced to treat hyperphosphatemia through the mechanism of action that tenapanor used; (ii) the FDA had not "indicated acceptance of in guidance[] or other documents" as a validated endpoint in that context; and (iii) greatly increased the risk that the FDA would reject the tenapanor NDA (which it did). Defendants had a duty to disclose that key distinction to make their statements about the relevant clinical data not misleading, and because they chose to speak about the purported findings of the relevant clinical data and thus had to speak the complete truth on that topic.

F. November 17, 2020 Investor Presentation

57. Defendant Raab and David Rosenbaum (who was the Company's Chief Development Officer) gave a presentation to investors, on behalf of Ardelyx, in question-and-answer format at the Jefferies Virtual London Healthcare Conference on November 17, 2020. Ardelyx published notice that the Company would be making that presentation – which it called a "fireside chat" – in a November 10, 2020 press release titled "Ardelyx to Present at the Jefferies Virtual London Healthcare Conference."

58. During the presentation, a participant asked about the clinical development program Ardelyx was conducting for the tenapanor NDA. In response, Mr. Rosenbaum stated that the data from the Phase 3 Trials established that administering tenapanor produced "a significant and clinically relevant phosphate lowering":

> Q – But David for the clinical program, I guess what is the goal? What is it that we're trying to do for these patients? And how in your view did your clinical program demonstrate do the achievement of those goals?
>
> A – [Mr. Rosenbaum] Sure. So first it's well known a lot of prospective observational studies that have shown an association with elevate[d] [serum phosphorus] and morbidity mortality. A lot of studies have shown that, so what our goal here is to lower serum phosphorus. And we've shown – we've run as Mike said three Phase 3 clinical trials two short term one long term. ***And what we've shown is that if you dose tenapanor [alone], you get a significant and clinically relevant phosphate lowering***. In our long-term phase 3, which is the most relevant study, we showed that 77% people administered tenapanor had a decrease in serum phosphorus and there was a 2 mg/dL decrease. So that's a very significant effect.
>
> . . . .
>
> And those on tenapanor, we automatically add tenapanor and allow them to titrate off of [sevelamer] to see how many we can get into the normal range. And people who end up studying from the beginning of freedom had a means prosperous of 7.27 mgs per deciliter. After mean duration of around 19 to 20 months, they went down to 4.94. And so they had over 2.3 mg definitely decrease and we were able to get up to 47% of those people into the normal range. So around the 60% increase over standard of core. ***So, what that – totality of that data [ha]s shown is that you can treat a lot of people with tenapanor alone and it will work well***.

[Emphasis added.]

59. The statements set out in ¶58 were materially false, misleading, incomplete, and inaccurate – both individually and in combination – because they conveyed that (i) administering tenapanor alone as a treatment for hyperphosphatemia in adult CKD patients on dialysis produced "a significant and clinically relevant phosphate lowering"; and (ii) "the totality of th[e] data" from the Phase 3 Trials showed that tenapanor alone "can treat a lot of people . . . and it will work well." In reality, as Defendants knew or recklessly disregarded, the Phase 3 Trials did not demonstrate that tenapanor as a monotherapy produced a clinically relevant or efficacious treatment effect in adult CKD patients on dialysis suffering from hyperphosphatemia. In fact, as Defendants knew and failed to disclose in connection with those representations, the Phase 3 Trials exclusively were basing their purported findings on trials that used only the surrogate endpoint of serum phosphates, which (i) never had been "the basis of approval or licensure (as applicable) of a drug" advanced to treat hyperphosphatemia through the mechanism of action that tenapanor used; (ii) the FDA had

not "indicated acceptance of in guidance[] or other documents" as a validated endpoint in that context; and (iii) greatly increased the risk that the FDA would reject the tenapanor NDA (which it did). Defendants had a duty to disclose that key distinction to make their statements about the relevant clinical data not misleading, and because they chose to speak about the purported findings of the relevant clinical data and thus had to speak the complete truth on that topic.

60. During the same presentation, a participant asked about the status of Ardelyx's tenapanor NDA, in response to which Defendant Raab stated that relevant divisions of the FDA "ha[d] already seen" certain information in the tenapanor NDA by virtue of the Company's prior submission of an NDA for tenapanor for the treatment of irritable bowel syndrome associated with constipation ("IBS-C"):

> Q – Okay. All right. Well very good. And so where the NDA submission is completed this point, right?
>
> A – [Defendant Raab] And we've been guiding the traditional 10 plus 2 PDUFA. Now the fact that we have, the idea CNDA is actually 10 month PDUFA, neither first the full 12. ***So, as we communicate and have people understand the FDA has already seen the entire CMC*** [Chemistry, Manufacturing, and Controls] ***package, but for the dosage forms***, 10 20 and 30, ***they've seen majority [of] the clinical data and in fact cardiorenal consulted with GI*** [the gastrointestinal division] ***on the green all studies that were in that data package. So we're quite confident with what it is that we've submitted***. The interactions as far with the agency have gone exceedingly well, will there be an inspection who knows with COVID (Technical Difficulty) person, the confidence I have in the team and the confidence with the fact that they've seen the majority of this helps a lot with the uncertainty we all feel until COVID has passed.

[Emphasis added.]

61. The statements set out in ¶60 were materially false, misleading, incomplete, and inaccurate – both individually and in combination – because they conveyed that by virtue of Ardelyx's prior submission of an NDA for tenapanor for the treatment of IBS-C, (i) the FDA's "cardiorenal [division] consulted with" its gastrointestinal division on "all studies that were in that data package" submitted in the prior NDA, meaning the FDA already had seen a "majority [of] the clinical data" involved in the current NDA; (ii) the FDA "ha[d] already seen the entire CMC package, but for the dosage forms," in the current NDA; and (iii) those facts made Defendants

"quite confident" in the NDA and underlying data at hand. Through those representations, Defendants misleadingly presented the FDA's prior approval of a distinct NDA for tenapanor as likely to have a meaningful, positive effect on the tenapanor NDA under review at that time. In reality, as Defendants knew or recklessly disregarded, the FDA approval that Ardelyx obtained for tenapanor for IBS-C – an entirely different indication – did not increase the likelihood that the FDA would approve Ardelyx's subsequent NDA for tenapanor for hyperphosphatemia because of the material differences between the respective Phase 3 development programs. For instance, the primary efficacy endpoints in the IBS clinical trials were clinical outcome endpoints, as they directly measured the patients' change in IBS symptoms. The primary efficacy endpoints in the hyperphosphatemia trials were surrogate endpoints, by contrast, as they measured changes in serum phosphates among patients. The inclusion and exclusion criteria of the trials also differed between the two programs. While the hyperphosphatemia trials excluded persons suffering from drug abuse or addiction within 12 months of study enrollment, the IBS trials had no such exclusion criterion. Moreover, the patients in the hyperphosphatemia trials were significantly older and suffered more clinical symptoms than the patients in the IBS trials. Also, the percentage of female patients in the IBS trials (roughly 80.7%) dwarfed its counterpart in the hyperphosphatemia trials (roughly 37%). In the light of those extensive, crucial differences, it was misleading for Defendants to state or suggest that the Company's previous tenapanor NDA for the IBS-C indication represented a meaningful means through which to positively affect the tenapanor NDA for hyperphosphatemia.

G. February 24, 2021 Investor Presentation

62. Defendant Raab gave a presentation to investors, on behalf of Ardelyx, in question-and-answer format at the 10th Annual SVB Leerink Global Healthcare Conference on February 24, 2021. Ardelyx published notice that the Company would be making that presentation – which it called a "fireside chat" – in a February 17, 2021 press release titled "Ardelyx to Present at the 10th Annual SVB Leerink Global Healthcare Conference."

63. During the presentation, Defendant Raab was asked about the status of Ardelyx's tenapanor NDA, in response to which he emphasized that certain divisions of the FDA "ha[d] already seen" a "good portion of this package" when Ardelyx previously had submitted an NDA for tenapanor for the treatment of IBS-C. Defendant Raab espoused points substantially similar to those he made at the November 17, 2020 investor call in which he partook months before, purporting to leverage Ardelyx's prior successful tenapanor NDA for IBS-C as a favorable indicator of things to come:

> Q – Maybe this is a good time to ask you about how NDA review is coming along and your confidence level and a timely approval, especially considering that at least in the last couple of months? Some companies saw delay due to COVID, do you worry about that at all?
>
> A – Yeah. I mean, we always worry. Because you don't know until you know. And I think we've got confidence in this though because ***remember that this is – tenapanor has already been approved for another indication***.
>
> ***So, this NDA is what the FDA has already seen, in fact cardio renal division consult to a GI*** [gastrointestinal] ***division for the approval of***. Now Ardelyx is sitting on the shelf, but the benefit of that process we went through both with the inspections that we went through, ***as well as cardio renal having seen a good portion of this package gives us confidence that the PDUFA date of April 29th is not something that had massive risk***.
>
> All the interactions that we've had thus far with the agency or standard ones that you have throughout the process requested the average data or clarifications, but there's been nothing unfold and anything that cause is concerned.

[Emphasis added.]

64. The statements set out in ¶63 were materially false, misleading, incomplete, and inaccurate – both individually and in combination – because they conveyed that by virtue of Ardelyx's prior submission of an NDA for tenapanor for the treatment of IBS-C, (i) "this NDA" for tenapanor for hyperphosphatemia was "what the FDA ha[d] already seen"; (ii) the FDA's "cardio renal division consult[ed]" with its "GI [gastrointestinal] division for the approval of" that previous NDA; and (iii) the "cardio renal" division already "having seen a good portion of this package" gave the Company "confidence." Through those representations, Defendants misleadingly presented the FDA's prior approval of a distinct NDA for tenapanor as likely to have

a meaningful, positive effect on the tenapanor NDA under review at that time. In reality, as Defendants knew or recklessly disregarded, the FDA approval that Ardelyx obtained for tenapanor for IBS-C – an entirely different indication – did not increase the likelihood that the FDA would approve Ardelyx's subsequent NDA for tenapanor for hyperphosphatemia because of the material differences between the respective Phase 3 development programs for hyperphosphatemia and IBS-C. For instance, the primary efficacy endpoints in the IBS clinical trials were clinical outcome endpoints, as they directly measured the patients' change in IBS symptoms. The primary efficacy endpoints in the hyperphosphatemia trials were surrogate endpoints, as they measured changes in serum phosphates among patients. The inclusion and exclusion criteria of the trials also differed between the two programs. While the hyperphosphatemia trials excluded persons suffering from drug abuse or addiction within 12 months of study enrollment, the IBS trials had no such exclusion criterion. Moreover, the patients in the hyperphosphatemia trials were significantly older and suffered more clinical symptoms than the patients in the IBS trials. Also, the percentage of female patients in the IBS trials (roughly 80.7%) dwarfed its counterpart in the hyperphosphatemia trials (roughly 37%).

65. In reality, as Defendants knew or recklessly disregarded, the FDA approval that Ardelyx obtained for tenapanor for an entirely different indication did not increase the likelihood that the FDA would approve Ardelyx's subsequent NDA for tenapanor for hyperphosphatemia given the inability of the Phase 3 Trials to achieve a clinically relevant or efficacious treatment effect in adult CKD patients on dialysis suffering from hyperphosphatemia, whether under a monotherapy or dual-mechanism approach.

H. March 8, 2021 Annual Report

66. On March 8, 2021, Ardelyx filed with the SEC on Form 10-K its fourth quarter and full year 2020 financial results ("FY20 10-K"), repeating substantially the same claims made in the Company's 2Q20 10-Q and 3Q20 10-Q with respect to the tenapanor NDA and underlying Phase 3 Trials. In relevant part, the FY20 10-K stated:

> ***The NDA is supported by three successful Phase 3 trials*** involving over 1,000 patients that evaluated the use of tenapanor for the control of serum phosphorus in

> CKD patients on dialysis, with two trials evaluating tenapanor as monotherapy and one trial evaluating tenapanor as part of a dual mechanism approach with binders.
>
> . . . .
>
> In December 2019, ***we reported statistically significant topline efficacy results from our second monotherapy Phase 3 clinical trial***, the PHREEDOM trial, which evaluated tenapanor for the control of serum phosphorus in CKD patients on dialysis. The PHREEDOM trial followed ***a successful monotherapy Phase 3 clinical trial completed in 2017, the BLOCK trial, which achieved statistical significance for the primary endpoint***. The only adverse event reported in these Phase 3 trials in less than 5% of patients was diarrhea, with an incidence rate of 52% in the PHREEDOM trial and 39% in the BLOCK trial, with most incidences in each trial being mild to moderate in nature. PHREEDOM is a one-year study with a 26-week open-label treatment period and a 12-week double-blind, placebo-controlled randomized withdrawal period followed by a 14-week open-label safety extension period. An active safety control group, for safety analysis only, received sevelamer, open-label, for the entire 52-week study period. Patients completing the PHREEDOM trial from both the tenapanor arm and the sevelamer active safety control arm had the option to participate in NORMALIZE, an ongoing open-label 18-month extension study.
>
> In June 2020, we announced positive results from a planned interim data analysis from our ongoing NORMALIZE extension study evaluating tenapanor, as monotherapy or in combination with sevelamer, to achieve serum phosphorus levels in the normal range (2.5 – 4.5 mg/dL) in patients with CKD on dialysis. The NORMALIZE extension study allowed patients from our PHREEDOM study to continue therapy with tenapanor and enabled those patients in the PHREEDOM safety control arm receiving sevelamer carbonate to transition to tenapanor. ***The data from the planned interim analysis demonstrated that the foundational use of tenapanor as monotherapy or in combination with sevelamer carbonate produces a significant phosphorus-lowering effect*** with a mean serum phosphorous reduction of 2.33 mg/dL, from a mean baseline phosphorus of 7.27 mg/dL at the beginning of the PHREEDOM trial to a mean of 4.94 mg/dL at the time of this analysis. . . .
>
> . . . .
>
> Tenapanor, if approved, would be the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake. It is not a phosphate binder. Tenapanor is a novel, potent, small molecule, that ***has been shown in phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach***.

[Emphasis added.]

67. The statements set out in ¶66 were materially false, misleading, incomplete, and inaccurate – both individually and in combination – because they conveyed that (i) the tenapanor "NDA is supported by three successful Phase 3 trials"; (ii) one such Phase 3 Trial, PHREEDOM, generated "statistically significant topline efficacy results"; (iii) another such Phase 3 Trial, described as a "successful monotherapy Phase 3 clinical trial," "achieved statistical significance for the primary endpoint"; (iv) Ardelyx "demonstrated that the foundational use of tenapanor as monotherapy or in combination with sevelamer carbonate produces a significant phosphorus-lowering effect"; and (v) tenapanor "has been shown in the phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach." In reality, as Defendants knew or recklessly disregarded, the Phase 3 Trials did not demonstrate that tenapanor produced a clinically relevant or efficacious treatment effect in adult CKD patients on dialysis suffering from hyperphosphatemia, whether under a monotherapy or dual-mechanism approach. In fact, as Defendants knew and failed to disclose in connection with those representations, the Phase 3 Trials measured only the surrogate endpoint of serum phosphates, which (i) never had been "the basis of approval or licensure (as applicable) of a drug" advanced to treat hyperphosphatemia through the mechanism of action that tenapanor used; (ii) the FDA had not "indicated acceptance of in guidance[] or other documents" as a validated endpoint in that context; and (iii) greatly increased the risk that the FDA would reject the tenapanor NDA (which it did). Defendants had a duty to disclose that key distinction to make their statements about the relevant clinical data not misleading, and because they chose to speak about the purported findings of the relevant clinical data and thus had to speak the complete truth on that topic.

I. April 29, 2021 Press Release

68. On April 29, 2021 – the date the FDA initially set as the operative PDUFA date for the tenapanor NDA – Ardelyx issued a press release announcing that the FDA made a formal request for additional information "***to help the agency better understand the clinical data in light of tenapanor's novel mechanism of action as compared to approved therapies***." The Company reported that it "submitted the requested analyses" to the FDA in response to the request, which

"constitute[d] a major amendment" to the NDA that required extending the PDUFA date "by three months" to July 29, 2021. [Emphasis added.]

69. Quoting Defendant Raab, the press release stated,

> "While disappointed in the delay, we understand the impact that the COVID-19 pandemic has had on the operations of the agency," said Mike Raab, president and chief executive officer of Ardelyx. "We appreciate the constructive labeling discussions with the agency over the past month and ***believe that the additional analyses submitted in response to recent dialogue with the agency reinforce the extensive clinical evidence we generated on tenapanor***. We look forward to continuing to work closely and constructively with FDA during the remainder of the review process. We are confident in the comprehensive data set, are well prepared for the launch of tenapanor upon potential approval and are dedicated to bringing this important medicine to patients."
>
> The NDA for tenapanor for the control of serum phosphorus is supported by a comprehensive development program involving more than 1,000 patients, including ***three Phase 3 clinical trials, all of which met their primary and key secondary endpoints***.

[Emphasis added.]

70. The statements set out in ¶69 were materially false, misleading, incomplete, and inaccurate – both individually and in combination – because they conveyed that (i) "additional analyses [Ardelyx] submitted in response to recent dialogue with the agency reinforce the extensive clinical evidence [Ardelyx] generated on tenapanor"; and (ii) the "three Phase 3 clinical trials[] all . . . met their primary and secondary endpoints." In reality, as Defendants knew or recklessly disregarded, the Phase 3 Trials did not demonstrate that tenapanor produced a clinically relevant or efficacious treatment effect in adult CKD patients on dialysis suffering from hyperphosphatemia, whether under a monotherapy or dual-mechanism approach. In fact, as Defendants knew and failed to disclose in connection with those representations, the Phase 3 Trials measured only the surrogate endpoint of serum phosphates, which (i) never had been "the basis of approval or licensure (as applicable) of a drug" advanced to treat hyperphosphatemia through the mechanism of action that tenapanor used; (ii) the FDA had not "indicated acceptance of in guidance[] or other documents" as a validated endpoint in that context; and (iii) greatly increased the risk that the FDA would reject the tenapanor NDA (which it did). Defendants had a duty to

disclose that key distinction to make their statements about the relevant clinical data not misleading, and because they chose to speak about the purported findings of the relevant clinical data and thus had to speak the complete truth on that topic

J. May 6, 2021 Quarterly Report

71. On May 6, 2021, Ardelyx filed with the SEC on Form 10-Q its first quarter 2021 financial results ("1Q21 10-Q"). With respect to the tenapanor NDA and underlying Phase 3 Trials, the Company repeated substantially the same claims made in its preceding quarterly SEC filings that spoke to the topic – that is, even though less than two weeks earlier the FDA formally requested more information "to better understand the clinical data" from those trials. The 1Q21 10-Q expressed nothing of substance about the FDA's information request, and stated, in relevant part:

> On April 29, 2021, the U.S. Food and Drug Administration ("FDA") determined that a submission we made in response to an information request from the FDA constituted a major amendment to our New Drug Application ("NDA") for tenapanor for the control of serum phosphorus, resulting in a three-month extension of the PDUFA date to July 29, 2021. ***The FDA's information request included a request for additional analyses of our clinical data***.
>
> . . . .
>
> In December 2019***, we reported statistically significant topline efficacy results from our second monotherapy Phase 3 clinical trial***, the PHREEDOM trial, which evaluated tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis. The PHREEDOM trial followed ***a successful monotherapy Phase 3 clinical trial completed in 2017, the BLOCK trial, which achieved statistical significance for the primary endpoint***. The only adverse event reported in these Phase 3 trials in less than 5% of patients was diarrhea, with an incidence rate of 52% in the PHREEDOM trial and 39% in the BLOCK trial, with most incidences in each trial being mild to moderate in nature. PHREEDOM is a one-year study with a 26-week open-label treatment period and a 12-week double-blind, placebo-controlled randomized withdrawal period followed by a 14-week open-label safety extension period. An active safety control group, for safety analysis only, received sevelamer, open-label, for the entire 52-week study period. Patients completing the PHREEDOM trial from both the tenapanor arm and the sevelamer active safety control arm had the option to participate in NORMALIZE, an ongoing open-label 18-month extension study.
>
> In June 2020, we announced positive results from a planned interim data analysis from our ongoing NORMALIZE extension study evaluating tenapanor, as monotherapy or in combination with sevelamer, to achieve serum phosphorus

> levels in the normal range (2.5 – 4.5 mg/dL) in patients with CKD on dialysis. The NORMALIZE extension study allowed patients from our PHREEDOM study to continue therapy with tenapanor and enabled those patients in the PHREEDOM safety control arm receiving sevelamer carbonate to transition to tenapanor. ***The data from the planned interim analysis demonstrated that the use of tenapanor as monotherapy or in combination with sevelamer carbonate produces a significant phosphorus-lowering effect*** with a mean serum phosphorous reduction of 2.33 mg/dL, from a mean baseline phosphorus of 7.27 mg/dL at the beginning of the PHREEDOM trial to a mean of 4.94 mg/dL at the time of this analysis. . . .
>
> . . . .
>
> Tenapanor is the first therapy for phosphate management that blocks phosphorus absorption at the primary pathway of uptake. It is not a phosphate binder. Tenapanor is a novel, potent, small molecule, that ***has been shown in phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach***.

[Emphasis added.]

72. The statements set out in ¶71 were materially false, misleading, incomplete, and inaccurate – both individually and in combination – because they conveyed that (i) one purportedly successful Phase 3 Trial, PHREEDOM, generated "statistically significant topline efficacy results"; (ii) another purportedly "successful monotherapy Phase 3 clinical trial," BLOCK, "achieved statistical significance for the primary endpoint"; (iii) Ardelyx "demonstrated that the foundational use of tenapanor as monotherapy or in combination with sevelamer carbonate produces a significant phosphorus-lowering effect"; and (iv) tenapanor "has been shown in the phase 3 studies to treat hyperphosphatemia as monotherapy and as a dual mechanism approach." In reality, as Defendants knew or recklessly disregarded, the Phase 3 Trials did not demonstrate that tenapanor produced a clinically relevant or efficacious treatment effect in adult CKD patients on dialysis suffering from hyperphosphatemia, whether under a monotherapy or dual-mechanism approach. In fact, as Defendants knew and failed to disclose in connection with those representations, the Phase 3 Trials measured only the surrogate endpoint of serum phosphates, which (i) never had been "the basis of approval or licensure (as applicable) of a drug" advanced to treat hyperphosphatemia through the mechanism of action that tenapanor used; (ii) the FDA had not "indicated acceptance of in guidance[] or other documents" as a validated endpoint in that

context; and (iii) greatly increased the risk that the FDA would reject the tenapanor NDA (which it did). Defendants had a duty to disclose that key distinction to make their statements about the relevant clinical data not misleading, and because they chose to speak about the purported findings of the relevant clinical data and thus had to speak the complete truth on that topic.

K. May 6, 2021 Press Release

73. As reported in the May 6, 2021 press release accompanying the Company's release of its First Quarter 2021 Financial Results, Defendant Raab offered an optimistic take on the FDA's request for clarifying information, stating in relevant part:

> "We continue to prepare for the potential approval and launch of tenapanor following the recent extension of our PDUFA date to July," said Mike Raab, president and chief executive officer of Ardelyx. "***We remain confident in the comprehensive data included in our New Drug Application*** and believe tenapanor represents an attractive alternative to currently available therapies to control serum phosphorus in CKD patients on dialysis. To that end, we are committed to working with the FDA through the completion of its review of our NDA and look forward to the possibility of making a significant impact in the lives of patients."

[Emphasis added.]

74. The statements set out in ¶73 were materially false, misleading, incomplete, and inaccurate – both individually and in combination – because they conveyed that the clinical trial "data included in [the Company's] New Drug Application" was "comprehensive." In reality, as Defendants knew or recklessly disregarded, the Phase 3 Trials did not demonstrate that tenapanor produced a clinically relevant or efficacious treatment effect in adult CKD patients on dialysis suffering from hyperphosphatemia. In fact, as Defendants knew and failed to disclose in connection with those representations, the Phase 3 Trials measured only the surrogate endpoint of serum phosphates, which (i) never had been "the basis of approval or licensure (as applicable) of a drug" advanced to treat hyperphosphatemia through the mechanism of action that tenapanor used; (ii) the FDA had not "indicated acceptance of in guidance[] or other documents" as a validated endpoint in that context; and (iii) greatly increased the risk that the FDA would reject the tenapanor NDA (which it did). Defendants had a duty to disclose that key distinction to make their statements about the relevant clinical data not misleading, and because they chose to speak

about the purported findings of the relevant clinical data and thus had to speak the complete truth on that topic.

IV. THE TRUTH EMERGES

75. Defendants' unduly rosy narrative came to a screeching halt after the markets closed on July 19, 2021. That day, Ardelyx announced the FDA sent the Company a letter six days earlier (on July 13, 2021) in which the FDA stated it identified "deficiencies" with respect to "***the size of the treatment effect and its clinical relevance***" according to the clinical trial data Ardelyx provided in the tenapanor NDA. [Emphasis added.]

76. The press release Ardelyx published on the topic stated, in relevant part:

> [T]oday [Ardelyx] announced that it received a letter from the U.S. Food and Drug Administration (the "FDA") on July 13, 2021, stating that, as part of its ongoing review of the company's New Drug Application ("NDA") for the control of serum phosphorus in adult patients with chronic kidney disease ("CKD") on dialysis, ***the FDA has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time***. The letter stated that the notification does not reflect a final decision on the information under review. The company immediately requested a meeting to discuss the deficiencies and was notified by the FDA today that the request for a meeting was denied.
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> While the FDA has not provided specific details regarding the deficiencies, ***the FDA noted that a key issue is the size of the treatment effect and its clinical relevance***.
>
> "This is an extremely disheartening and disappointing communication from the FDA, particularly following the weeks of label discussions that occurred in early April, the fact that our NDA submission included three pivotal trials across 1,000 patients, all which met their primary and key secondary endpoints, as well as the additional data analyses we submitted in late April in response to the FDA's requests," said Mike Raab, president and chief executive officer of Ardelyx. "We plan to work with the FDA to learn more about the identified deficiencies and will seek to resolve them as quickly as possible."

[Emphasis added.]

77. On this news, the price of Ardelyx's shares plunged from their July 19, 2021 closing price of $7.70 per share to a July 20, 2021 close of just $2.01 per share. This represents a one-day drop of nearly 74%, or hundreds of millions of dollars in lost market capitalization.

78. Then, on July 29, 2021 – the operative PDUFA date following the major amendment to the NDA Ardelyx reported on April 29, 2021 – the Company issued a press release announcing that it "***received a Complete Response Letter***" from the FDA in response to the tenapanor NDA. A Complete Response Letter is a response to an NDA by which the FDA tells a drug sponsor its review of the NDA is complete and the agency is not approving the application. The relevant press release was titled "Ardelyx Receives Complete Response Letter from U.S. FDA for New Drug Application for Tenapanor for the Control of Serum Phosphorus in Adult Patients with CKD on Dialysis." [Emphasis added.]

79. According to Ardelyx, in relevant part, the Complete Response Letter stated the FDA determined "***the magnitude of the treatment effect***" shown in the tenapanor NDA and underlying clinical trial data was "***small and of unclear clinical significance***":

> [T]oday [Ardelyx] announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the company's New Drug Application (NDA) for tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis.
>
> According to the CRL, while the FDA agrees that "the submitted data provide substantial evidence that tenapanor is effective in reducing serum phosphorus in CKD patients on dialysis," ***they characterize the magnitude of the treatment effect as*** "***small and of unclear clinical significance***." Additionally, the FDA noted that for the application to be approved, Ardelyx needs "to conduct an additional adequate and well-controlled trial ***demonstrating a clinically relevant treatment effect on serum phosphorus or an effect on the clinical outcome thought to be caused by hyperphosphatemia in CKD patients on dialysis***." There were no safety, clinical pharmacology/biopharmaceutics, CMC [chemistry, manufacturing, and controls] or non-clinical issues identified in the CRL.
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> . . . .
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> "We are saddened by this communication from the FDA and what it means for the patients and the physicians who treat them," said Mike Raab, president and chief executive officer of Ardelyx. "We continue to believe tenapanor represents an important, first-in-class treatment option for patients with elevated phosphorus. We do not agree with the FDA's subjective assessment on ***the clinical relevance of the treatment effect of tenapanor in our studies which met all clinical endpoints agreed upon by the FDA***. In our view, the serum phosphorus lowering data generated with tenapanor in all of our clinical studies is meaningful and clinically significant. We will work with the agency to address the issues raised and, to the extent possible, find an expeditious path forward."

[Emphasis added.]

80. The Company convened a conference call with investors later that day to discuss the issuance of the CRL. On the call, Defendant Raab repeatedly represented that ***the FDA had authorized, and even helped design, the clinical trials*** it now found incapable of demonstrating a clinically relevant treatment effect of tenapanor for hyperphosphatemia in adult CKD patients on dialysis:

> How we got here sales comprehension, especially considering the extensive and comprehensive clinical evaluation of tenapanor with three successful Phase 3 trials, all of us which met primary and key secondary endpoints with statistical significance compared to placebo and long-term safety demonstrated versus inactive safety control, ***all three Phase 3 trials were designed and agreed upon in collaboration with the FDA***, not to mention that tenapanor was approved in September 2019 to treat irritable bowel syndrome and constipation in adults.
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> . . . .
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> The clinical data supporting our NDA involve over 1000 patients and included two Phase 3 monotherapy trials and a Phase 3 trial of tenapanor in combination with binder therapy. Our development program encompassed years of clinical investigation and valuation. ***As you would expect, all of our trial designs were discussed and shared with the FDA every step of the way***. Results from a rigorous statistical analysis plan demonstrated clear, unambiguous, and consistent safety and efficacy of tenapanor in reducing serum phosphorus. Furthermore, we continue to develop and share more supportive data from our ongoing Phase 4 studies normalized and optimized at international medical and scientific meetings.
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> . . . .
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> ***During each step of development, we reviewed our trial designs with statistical analysis plans with the FDA***, including powering the freedom study to achieve at least a 1 milligram per deciliter decrease in serum phosphorus which tenapanor readily achieved. These interactions coupled with the scenes[ph] approval of tenapanor or IBSC, let us to feel quite confident heading into the NDA process for the use of tenapanor in hyperphosphatemia.

[Emphasis added; alteration in original.]

81. During the question-and-answer segment of that conference call, a participant asked the pointed question: "Are we hearing that maybe [the FDA's] cardiorenal [division] was maybe reconsidering whether or not phosphorous is an approval biomarker?" Defendant Raab answered:

> I think what we're hearing is the heart of [cardio]renal [division] ***inherited phosphorus as a biomarker that has been used to approve other products***. I think what I'm hearing is, ***they're not seeing or believing in the clinical relevance of the effects***, although they say in their letter, and we've hit every single endpoint. I think they're asking us to prove something potentially that I was haven't – had to prove but not knowable until we had the type A meeting.

[Emphasis added.]

82. Months later, during an investor presentation at the Jeffries London Healthcare Virtual Conference on November 18, 2021, Defendant Raab said the FDA's decision reflected the agency having "***moved the goalposts*** on [the Company]":

> [A –] We clearly have a statistically significant impact on decreasing serum phosphorus whether it's a monotherapy or when you're adding it [with] binders and you're having an impact and physicians should be able to make those decisions based upon what the clinical data are that you have generated [your] clinical studies. ***They have moved the goalposts on us***, implying that they would expect an outcome type study which has never been required for phosphorus lowering drugs and that's a big part of our approach is to see this is an acceptable endpoint. We hit the endpoint as we discussed and agreement is physical analysis plan. So we should address this in labeling and make sure that we have something that allows physicians to make a determination as to which patients are going to benefit from this.
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> . . . .
>
> [Q –] Okay, all right. And so, like what would be, you know to the extent that you can. Could you speculate on the things that somebody like a Peter Stein [Director of the Office of New Drugs of the FDA's Center for Drug Evaluation and Research] would take into account during their assessment?
>
> [A –] I think everything we just talked about, right. ***This is a program that followed the rules***, right, and ***provided results that by any measure should have resulted in an approval, but for the fact that this division is not keen on surrogate endpoints, the biomarkers***. This is the Cardio Renal Division inherited hyperphosphatemia from the metabolic endocrine division and have only approved two other drugs, Velphoro and Auryxia. But those are binders, right, and that was the rationale, that's within a family or a class of drugs and similar endpoint. We're a new mechanism of action and different biology, and I think gave them the opportunity, if you could say it that way, to then hold us to a different standard, which is my speculation on, so what a Peter Stein would do is look at what we generated, and the argument that we will pose is that having followed all the rules and hit the endpoints as anticipated, this is a drug that is approvable.

[Emphasis added.]

83. Thus, according to Defendants, the FDA's decision on the tenapanor NDA was caused by the FDA "mov[ing] the goalposts" on the agency's view of using serum phosphorus levels as a surrogate endpoint in the Phase 3 Trials. Defendants maintain that explanation even though (i) the FDA purportedly authorized and agreed to using that very surrogate endpoint in the Phase 3 Trials; (ii) Defendants knew that the FDA division with which they were dealing merely "inherited phosphorus as a biomarker that ha[d] been used to approve other products"; (iii) Defendants knew that the "other products" that obtained approval despite using serum phosphorus levels as a surrogate endpoint dramatically differed from tenapanor because their "mechanism of action" was the incumbent binding to phosphates, as opposed to tenapanor's novel inhibiting of phosphate absorption; (iv) Defendants knew that the FDA division with which they were dealing was "not keen on surrogate endpoints"; (v) with respect to the acceptability of even the validated (or otherwise approved) surrogate endpoints enumerated in the FDA's table, Defendants knew (or were reckless in not knowing) the FDA unequivocally warns that acceptability in a given clinical program depends on the "***therapeutic mechanism of action***" of the proffered drug, among other factors. [Emphasis added.]

V. ADDITIONAL SCIENTER ALLEGATIONS

84. As alleged herein, Defendants acted with scienter in that they: (i) knew that the public documents and statements issued or disseminated in the name of the Company were materially false, misleading, and incomplete when made; (ii) knew that such statements or documents would be issued or disseminated to the investing public; and (iii) knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. The Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding the Phase 3 Trials data, their control over, and/or receipt and/or modification of Ardelyx's allegedly materially false, misleading, and incomplete statements and/or their associations with the Company that made them privy to confidential proprietary information concerning Ardelyx, participated in the fraudulent scheme alleged herein.

85. Specifically, at all relevant times, Defendants knew (or recklessly disregarded) that the purportedly successful Phase 3 Trials were incapable of demonstrating a clinically relevant treatment effect sufficient to deliver, or be likely to deliver, FDA approval of the tenapanor NDA. Despite that, Defendants serially brandished the Phase 3 Trials as showing that tenapanor delivered a successful and clinically relevant treatment of hyperphosphatemia in adult CKD patients on dialysis, even after the FDA requested clarifying information that supposedly disrupted the parties' label discussions.

86. Moreover, scienter can be inferred from the importance of obtaining FDA approval for tenapanor to treat hyperphosphatemia in adult CKD patients on dialysis to the "core operations" of Ardelyx. For example, as the Company stated in both its 2Q20 10-Q and 3Q20 10-Q, Ardelyx's "portfolio is led by the development of tenapanor, a first-in-class medicine for the control of serum phosphorus in adult patients with CKD on dialysis." Further, although Ardelyx previously obtained FDA approval of its NDA tenapanor for the treatment of IBS-C, Ardelyx "ha[s] not generated any revenues from product sales" yet, as both the 2Q20 10-Q and 3Q20 10-Q indicated. Recognizing the commercial importance of tenapanor to Ardelyx, Defendant Raab emphasized that the Company had become "well positioned and well prepared to commercialize tenapanor upon potential FDA approval of the first and only phosphate absorption inhibitor for the control of serum phosphorus" in a March 8, 2021 press release titled "Ardelyx Reports Fourth Quarter and Full Year 2020 Financial Results and Recent Highlights." At bottom, at all relevant times, obtaining FDA approval for tenapanor for hyperphosphatemia was critical to Ardelyx's commercial prospects.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

87. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 86 above as if fully set forth herein.

88. Plaintiff brings this action as a class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of a class consisting of all those who purchased or

otherwise acquired Ardelyx's common stock during the Class Period and were damaged upon the revelation of the alleged corrective disclosure ("Class").

89. Excluded from the Class are: (i) Defendants; (ii) present or former executive officers of Ardelyx, members of the Company's Board of Directors, and members of their immediate families (as defined in 17 C.F.R. §229.404, Instructions (1)(a)(iii) and (1)(b)(ii)); (iii) any of the foregoing persons' legal representatives, heirs, successors, or assigns; and (iv) any entities in which Defendants have or had a controlling interest, or any affiliate of Ardelyx.

90. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's common stock was actively traded on the NASDAQ, a national securities exchange in the United States. While the exact number of Class members is unknown to Plaintiff at this time, and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the Class. Millions of Ardelyx shares were publicly traded during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Ardelyx or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

91. Plaintiff's claims are typical of the claims of Class members because all members of the Class are similarly affected by Defendants' wrongful conduct in violation of the federal securities laws as alleged herein.

92. Plaintiff will fairly and adequately protect the interests of Class members, and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

93. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the members of the Class are:

(a) whether Defendants violated the Exchange Act as alleged herein;

(b) whether Defendants' statements to the investing public during the Class Period omitted and/or misrepresented material facts about the Company;

(c) whether Defendants' statements to the investing public during the Class Period omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether Defendants Raab and Renz caused Ardelyx to issue false and misleading statements during the Class Period;

(e) whether Defendants acted knowingly or recklessly in issuing false and misleading statements;

(f) whether the price of Ardelyx's common stock was artificially inflated; and

(g) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

94. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy, since joinder of all members is impracticable.

95. Further, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

PRESUMPTION OF RELIANCE

96. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) Ardelyx's common stock is traded in an efficient market;

(d) the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;

(e) the Company's securities were traded on the NASDAQ in the United States;

(f) the Company was covered by securities analysts;

(g) the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

(h) Plaintiff and members of the Class purchased, acquired, and/or sold Ardelyx's common stock between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed without knowledge of the omitted or misrepresented facts

97. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

98. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

CLAIMS FOR RELIEF

COUNT I

Violations of §10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)

99. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 98 above as if fully set forth herein.

100. This Count is asserted on behalf of all members of the Class against Ardelyx and the Individual Defendants for violations of §10(b) of the Exchange Act (15 U.S.C. §78(b)) and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

101. During the Class Period, Defendants engaged in a plan, scheme, conspiracy, and course of conduct pursuant to which they knowingly or recklessly engaged in acts, transactions, practices, and courses of business that operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under

which they were made, not misleading; and employed devices, schemes, and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Ardelyx's common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Ardelyx's common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants took the actions set forth herein.

102. Pursuant to the above plan, scheme, conspiracy, and course of conduct, Defendants participated directly or indirectly in the preparation and/or issuance of the annual reports, SEC filings, press releases, and other statements and documents, as described above, including statements made to securities analysts and the media, that were designed to influence the market for Ardelyx's common stock. Such reports, filings, releases, and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Ardelyx's business and operations.

103. By virtue of their positions at Ardelyx, Individual Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Individual Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Individual Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted, as described above.

104. Further information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As senior managers and/or directors of Ardelyx, the Individual Defendants had knowledge of the details of Ardelyx's internal affairs.

105. Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, Defendants Raab and Renz were able to, and did, directly or indirectly, control the content of the statements of Ardleyx. As officers and/or directors of a publicly held company, Defendants Raab and Renz had a duty to disseminate timely, accurate, truthful, and complete information with respect to Ardelyx's businesses, operations, future financial condition, and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases, and public statements, the market price of Ardelyx's common stock was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Ardelyx's business and financial condition, which were concealed by Defendants, Plaintiff and other members of the Class purchased or otherwise acquired Ardelyx's common stock at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities, and/or statements disseminated by Defendants, and were damaged thereby.

106. During the Class Period, Ardelyx's common stock was traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which Defendants made, issued, or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired Ardelyx's common stock at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said common stock, or would not have purchased or otherwise acquired shares at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Ardelyx's common stock was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Ardelyx's common stock declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

107. By reason of the conduct alleged herein, Defendants have knowingly or recklessly, directly or indirectly, violated §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

108. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

109. This action was filed within two years of discovery of the fraud and within five years of Plaintiff's purchase of securities giving rise to the cause of action.

COUNT II

Violations of §20(a) of the Exchange Act (Against the Individual Defendants)

110. Plaintiff repeats and realleges each and every allegation contained in paragraphs 1 through 109 above as if fully set forth herein.

111. During the Class Period, the Individual Defendants participated in the operation and management of Ardelyx and conducted and participated, directly and indirectly, in the conduct of Ardelyx's business affairs. Because of his senior positions as the Company's CEO and President, Defendant Raab knew of the materially false and misleading information alleged herein. Similarly, because of his senior position as the Company's CFO, Defendant Renz knew of the materially false and misleading information alleged herein.

112. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information, with respect to Ardelyx's business practices, and promptly correct any public statements issued by Ardelyx that had become materially false or misleading.

113. Because of their positions of control and authority as senior directors and/or officers and/or executive team members of the Company, the Individual Defendants were able to, and did, control the contents of the various reports, press releases, and public filings that Ardelyx disseminated in the marketplace during the Class Period concerning the Company's business, operations, and tenapanor NDA. Throughout the Class Period, Individual Defendants exercised their power and authority to cause Ardelyx to engage in the wrongful acts complained of herein.

Individual Defendants, therefore, were each a "controlling person" of Ardelyx within the meaning of §20(a) of the Exchange Act. In this capacity, Individual Defendants participated in the unlawful conduct alleged herein that artificially inflated the market price of Ardelyx's common stock.

114. Individual Defendants, therefore, each acted as a controlling person of Ardelyx. By reason of their senior management positions and/or being a director of Ardelyx, Individual Defendants had the power to direct the actions of, and exercised the same, to cause Ardelyx to engage in the unlawful acts and conduct complained of herein. Individual Defendants exercised control over the general operations of Ardelyx and possessed the power to control the specific activities that comprise the primary violations about which Plaintiff and the other members of the Class complain.

115. As set forth above, Ardelyx and the Individual Defendants each violated §10(b) and Rule 10b-5 promulgated thereunder by their acts and omissions, as alleged in this complaint.

116. By reason of the above conduct and by virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiff and the other members of the Class have suffered damages in connection with their purchases of the Company's securities.

117. This action is filed within two years of discovery of the fraud and within five years of Plaintiff's purchase of securities giving rise to the cause of action.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that the instant action may be maintained as a class action under Fed. R. Civ. P. 23 and certifying Plaintiff as Class Representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class pre- and post-judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and

D. Awarding Plaintiff and the other Class members such other relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff hereby demands a trial by jury on all issues so triable.

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